

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

<b>IN RE: TAXOTERE (DOCETAXEL)</b>	)	<b>MDL No. 16-2740</b>
<b>PRODUCTS LIABILITY</b>	)	
<b>LITIGATION</b>	)	<b>SECTION: “H” (5)</b>
	)	
<b>This document relates to:</b>	)	
Elizabeth Kahn, 16-17039	)	

## ORDER AND REASONS

Before the Court is a Motion for Reconsideration on Warnings Causation (Doc. 12536). On May 26, 2021, the Court held oral argument on the Motion. For the following reasons, the Motion is **DENIED**.

## BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,<sup>1</sup> that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, “Sanofi” or “Defendants”). Plaintiffs allege that the drug caused permanent alopecia, or permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second is set for August 23, 2021.<sup>2</sup>

Plaintiff Elizabeth Kahn is the designated plaintiff for the second bellwether trial. In its Order and Reasons dated April 7, 2020 (Doc. 9888) (the

<sup>1</sup> Docetaxel is the generic version of Taxotere.

<sup>2</sup> The second trial was continued due to the COVID-19 pandemic.

“Order”), the Court ruled on Sanofi’s Motion for Summary Judgment Based on Warnings Causation as to Kahn.<sup>3</sup> Applying the learned intermediary doctrine, the Court considered whether a different warning in the Taxotere label would have changed the prescribing decision of Kahn’s oncologist, Dr. Carl Kardinal. The Court considered whether Dr. Kardinal would have warned Kahn of a risk of permanent alopecia had he known of it, and the Court considered “how patient choice then would have steered the conversation and the ultimate prescribing decision.”<sup>4</sup> The Court cited testimony from Dr. Kardinal saying that he would have told Kahn of such a risk and would have discussed other options with her had she not wished to take Taxotere. Then, the Court cited testimony from Kahn saying that if she was told that Taxotere carried a risk of permanent hair loss, she would have asked about other options. Based on this, the Court found that there was a genuine issue of fact on causation.

In the instant Motion, Sanofi now asks the Court to reconsider its Order based on a recent Fifth Circuit decision. Plaintiff opposes the Motion.

### **LEGAL STANDARD**

A motion to reconsider an interlocutory order is governed by Federal Rule of Civil Procedure 54(b), which states that “any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties’ rights and liabilities.” “Under Rule 54(b), ‘the trial court is free to reconsider and reverse its decision

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<sup>3</sup> The Court granted the Motion in part and dismissed Plaintiff’s redhibition claim. Sanofi seeks reconsideration only insofar as the Court denied the Motion.

<sup>4</sup> Doc. 9888 at 4.

for any reason it deems sufficient, even in the absence of new evidence or an intervening change in or clarification of the substantive law.”<sup>5</sup> “[T]he power to reconsider or modify interlocutory rulings is committed to the discretion of the district court, and that discretion is not cabined by the heightened standards for reconsideration governing final orders.”<sup>6</sup>

### LAW AND ANALYSIS

Sanofi argues that the Fifth Circuit has now established the causation standard relevant to this litigation. Sanofi avers that the dispositive question is whether the physician would have changed his prescribing decision had he been given a different warning, and Sanofi asserts that the Fifth Circuit rejected the notion that the inquiry should consider how patient choice would have steered the conversation between the patient and her doctor.

The Court finds no reason to reverse its original decision. As set forth in the Order at issue, under Louisiana law, failure to warn claims involving prescription drugs are subject to the learned intermediary doctrine.<sup>7</sup> Under the doctrine, the manufacturer of a prescription drug “has no duty to warn the patient, but need only warn the patient’s physician.”<sup>8</sup> In other words, a manufacturer’s duty runs only to the physician—the learned intermediary.<sup>9</sup>

The Fifth Circuit has held that there is a two-prong test governing inadequate warning claims under the Louisiana Products Liability Act (LPLA) when the learned intermediary doctrine is applicable:

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<sup>5</sup> *Austin v. Kroger Texas, L.P.*, 864 F.3d 326, 336 (5th Cir. 2017) (quoting *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167, 185 (5th Cir. 1990)).

<sup>6</sup> *Id.* (quoting *Saint Annes Dev. Co. v. Trabich*, 443 F. App’x 829, 831–32 (4th Cir. 2011)).

<sup>7</sup> *Grenier v. Med. Eng’g Corp.*, 99 F. Supp. 2d 759, 765 (W.D. La. 2000) (applying Louisiana law), *aff’d*, 243 F.3d 200 (5th Cir. 2001).

<sup>8</sup> *Willett v. Baxter Intern., Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991).

<sup>9</sup> *Grenier*, 99 F. Supp. 2d at 766.

First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.<sup>10</sup>

Regarding the second prong, the law is well established that, to prove causation, “the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product.”<sup>11</sup>

As Sanofi notes, the Fifth Circuit recently issued a ruling relating to a case in this MDL—*June Phillips v. Sanofi U.S. Services, et al.*<sup>12</sup> Applying the learned intermediary doctrine in the chemotherapy context, the court noted that while “[t]he decision to use a drug in a particular circumstance rests with [both] the doctor and the patient,”<sup>13</sup> a causation analysis must focus on “the prescribing physician’s decision to prescribe the drug.”<sup>14</sup> The court wrote:

[T]o the extent that patient choice is relevant, that relevance is cabined to helping us decide whether [the plaintiff’s] evidence—including that of other available treatments and the importance she places on her appearance—is sufficient to introduce a genuine dispute of material fact as to whether [the physician’s]

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<sup>10</sup> *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 265–66 (5th Cir. 2002) (internal citation omitted).

<sup>11</sup> *Willett*, 929 F.2d at 1099. *See also* *Pellegrin v. C.R. Bard*, 2018 WL 3046570, at \*4 (E.D. La. June 20, 2018).

<sup>12</sup> *In re Taxotere (Docetaxel) Prods. Liab. Litig. (June Phillips v. Sanofi U.S. Services, et al.)*, No. 20-30405, 2021 WL 1526429 (5th Cir. Apr. 19, 2021).

<sup>13</sup> *Id.* at \*3 (quoting *Calhoun v. Hoffman-La Roche, Inc.*, 768 So. 2d 57, 59 n.1 (La. App. 1 Cir. 2000), *writ denied*, 765 So. 2d 1041 (La. 2000)).

<sup>14</sup> *Id.* The Court acknowledges the clarification from the Fifth Circuit in Footnote 4 of its opinion, providing that the question is not “whether and how the doctor would have advised the patient of the risk of permanent alopecia associated with Taxotere, whether the patient would have inquired about other options, what the doctor would have recommended, and what decision the plaintiff would have ultimately made.” *Id.* at \*3 n.4.

prescribing decision would have been different had *he* known that Taxotere’s associated risk of alopecia was potentially permanent rather than temporary.<sup>15</sup>

Against this backdrop, the Fifth Circuit considered the facts before it.

First, the court considered whether a warning regarding permanent alopecia would have altered the physician’s risk-benefit assessment of Taxotere or his opinion that Taxotere was the best treatment for Phillips, the plaintiff.<sup>16</sup> The court answered no to both.<sup>17</sup> Next, the court considered whether there was any evidence that the plaintiff “might have steered the conversation in such a way that [her oncologist] would have changed his prescribing decision had he known that the risk of alopecia associated with Taxotere was potentially permanent rather than temporary.”<sup>18</sup> The court found “no indication that [the plaintiff] investigated or asked about alternatives that might avoid the abnormal hair growth or hair loss.”<sup>19</sup> Instead, the court found that the plaintiff “put her faith in [her physician],’ and consented to treatment.”<sup>20</sup> Finding insufficient evidence to create an issue of fact on causation, the court affirmed summary judgment for Sanofi.<sup>21</sup>

With this guidance in mind, the Court now turns to Plaintiff’s oncologist, Dr. Kardinal. Like the oncologist in *Phillips*, Dr. Kardinal testified that if the Taxotere label had warned of permanent alopecia, this would not have changed his chemotherapy recommendation for Plaintiff Kahn.<sup>22</sup> He testified, however, that such a risk “would have to be included in the discussion” with a patient.<sup>23</sup>

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<sup>15</sup> *Id.*

<sup>16</sup> *See id.* at \*4.

<sup>17</sup> *See id.*

<sup>18</sup> *Id.* at \*4.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *See id.* at \*5.

<sup>22</sup> Doc. 9300-9 at 15.

<sup>23</sup> Doc. 9422-4 at 13.

He testified unequivocally that “if [Sanofi] stated that the incidence of permanent hair loss were X percent or whatever, those things should be made known to the patient.”<sup>24</sup> Dr. Kardinal further stated that if a patient did not wish to take Taxotere because of such a risk, he would have discussed other options with her. He stated that paclitaxel is an adequate alternative to Taxotere in terms of its efficacy,<sup>25</sup> and the Court has found no evidence in the record suggesting that paclitaxel was unsuitable for Plaintiff Kahn. This is distinguishable from *Phillips*, in which the identified alternatives were not suitable for the plaintiff due to her age and pre-existing heart conditions.<sup>26</sup>

Now, like the Fifth Circuit, the Court considers whether there is any evidence that Plaintiff Kahn “might have steered the conversation in such a way that [her oncologist] would have changed his prescribing decision had he known that the risk of alopecia associated with Taxotere was potentially permanent rather than temporary.”<sup>27</sup> According to Kahn’s testimony, Dr. Kardinal told Kahn that her hair loss would be temporary, and a certain nurse assured Kahn of this.<sup>28</sup> Kahn testified as follows:

A: [O]ne day, during one of my early visits with Dr. Kardinal and the clinical trial nurse, my husband and I were waiting in the waiting room . . . . And [the nurse] says, I want you to meet someone. I have another patient here . . . , and I want you to see how her hair is growing back. And your hair is going to grow back exactly like

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<sup>24</sup> Doc. 9300-9 at 18.

<sup>25</sup> Doc. 9422-4 at 13–14.

<sup>26</sup> See *Phillips*, 2021 WL 1526429 at \*4 (“[T]hese alternatives to the Taxotere-based TCH carried a risk of cardio toxicity and are not recommended for use in those over the age of sixty-five. In light of the fact that Phillips was seventy-five and had pre-existing heart conditions, Dr. Sonnier did not prescribe these alternatives. Dr. Sonnier testified that had Phillips asked to undergo an Anthracycline-based therapy instead of TCH, he ‘[didn’t] think it would have been okay with [him],’ and he ‘would not give it.’”).

<sup>27</sup> *Id.*

<sup>28</sup> Doc. 9422-6 at 18, 32–33.

that, too. You're going to have a full head of hair when you're finished with chemotherapy.

Q: Who said that to you?

A: My clinical trial nurse.

Q: What was her name?

A: That would have been Shevonda.<sup>29</sup>

As this Court noted in its original Order, Plaintiff Kahn testified that if instead she “was told that Taxotere could have caused permanent hair loss, [she] would have asked what [her] other options were.”<sup>30</sup> Notably, when Kahn was given options regarding her initial treatment, she chose not to have a mastectomy; instead, she chose to see if chemotherapy would shrink her tumor, which it did, thereby allowing her to have a lumpectomy instead.<sup>31</sup> This is relevant to “the importance she places on her appearance,”<sup>32</sup> and this further suggests that Kahn would have explored her options with Dr. Kardinal.

Considering the evidence, the Court finds that there are fact issues for the jury to decide regarding whether Dr. Kardinal, after discussing with Plaintiff Kahn the risks and benefits of her viable treatment options, would have changed his decision to prescribe Taxotere to her.

### CONCLUSION

Accordingly, for the foregoing reasons, Sanofi's Motion for Reconsideration on Warnings Causation (Doc. 12536) is **DENIED**.

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<sup>29</sup> *Id.*

<sup>30</sup> Doc. 9888 at 5. *See also* Doc. 9422-6 at 33. Kahn's deposition testimony suggests that because she was assured her hair loss would be temporary, she did not ask about any options that would avoid permanent hair loss. *Id.* at 37.

<sup>31</sup> Doc. 9888 at 5.

<sup>32</sup> *Phillips*, 2021 WL 1526429, at \*3.

New Orleans, Louisiana this 14th day of July, 2021.

A handwritten signature in black ink, appearing to read "Jane Milazzo", written over a horizontal line.

JANE TRICHE MILAZZO  
UNITED STATES DISTRICT JUDGE